REMARKS

This Amendment is fully responsive to the Office Action mailed April 21, 2011. It is respectfully submitted that the claims recite statutory subject matter and contain limitations that patentably define over the references cited in the Office Action, for the reasons discussed in these remarks. Therefore, reconsideration and allowance of the pending claims is appropriate and respectfully requested.

Rejection of Claims 1-18 Under 35 U.S.C. § 112, ¶ 2

The Office Action (page 2) rejects claims 1-18 under 35 U.S.C. § 112, ¶ 2, on two separate bases.

The first basis is an insufficient antecedent basis for "the associated imaging device" in independent claims 1 and 10. Those claims have been amended herein to replace that term with "the imaging device." Claims 1 and 10 have similarly been amended to replace "the associated human operator" with "the associated operator", for similar reasons.

The second basis is an insufficient antecedent basis for "along a selected linear path" in lines 17-18 of claim 1. This rejection is respectfully traversed. The "selected linear path" limitation appears twice in claim 1, as reproduced here with emphasis added:

> a holding area formed at a second end of the main body portion, the holding area holding the medical device in an orientation suitable for motion relative to said patient **along a selected linear path**, the guide apparatus being operative to translate the medical device **along said selected linear path** in response to manual force applied by the associated operator at said gripping area during insertion of the medical device as restricted by the linear slider mechanism.

The Office Action apparently objects to the first appearance of this limitation, as it is the one that appears at lines 17-18 of claim 1 in Amendment C filed on October 25, 2010. But, because that limitation recites "a" selected linear path rather than "the" or "said" selected linear path, no antecedent basis is required. Moreover, the "selected linear path" may in some embodiments be different from the "single linear path" recited earlier in the claim. By way of reference to the embodiment shown in Figure 3 of the application, the "selected linear path" is identified as "P" and the "single linear path" is identified as "B". See Application, at page 8, lines 13-31. In other

embodiments, the "selected linear path" may be the same as the "single linear path", but that is not required by claim 1.

In addition, claims 5 and 14 are amended to depend from parent claims containing proper antecedent basis for all claim limitations.

For these reasons, reconsideration and withdrawal of the claim rejections based on 35 U.S.C. § 112, ¶ 2 is respectfully requested.

Rejection of Claims 1-20 Under 35 U.S.C. § 101

The Office Action (pages 3-4) rejects all claims 1-20 under 35 U.S.C. § 101 as directed to non-statutory subject matter. Specifically, the Office Action concludes "[t]he claims encompass a human and living subject matter, which is not a result of human intervention, and therefore is not patentable subject matter." These rejections are respectfully traversed, for the following reasons.

The claims define a "machine" and/or a "manufacture" under 35 U.S.C. § 101. Claim 1 recites, for example, "a system for inserting a medical device into a patient" including a "guide apparatus" having "a connector portion", "a main body portion", "a gripping area" and "a holding area", among other limitations. Corresponding limitations can be found in the other independent claims. None of those limitations recites living subject matter. In this regard, the only authority relied upon in the Office Action is 35 U.S.C. § 101 and MPEP § 2105. That portion of the MPEP is entitled "Patentable Subject Matter - Living Subject Matter" and focuses on the "manufacture" portion of § 101. In particular, section 2105 of the MPEP provides that a "manufacture" is "the production of articles for use from raw materials prepared by giving to these materials new forms, qualities, properties, or combinations whether by hand labor or machinery" (relying on Diamond v. Chakrabarty, 447 U.S. 303 (1980)). It further provides a "nonnaturally occurring manufacture or composition of matter — a product of human ingenuity — having a distinctive name, character, [and] use" is patentable subject matter. Applying those standards, the pending claims 1-20 define patentable subject matter.

MPEP § 2105 additionally states: "If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. § 101 must be made . . . ." However, that is not the case here, where the claims recite several limitations which cannot under any circumstance be construed to encompass a human being. These limitations

include, for example, "an imaging device scanning the patient to generate a volumetric image data set of the patient", "a human readable device for displaying an image of the patient derived from said volumetric image data set", "means for selecting a virtual trajectory", "robotic means", "a guide apparatus", "a connector portion" and "a linear slider mechanism."

It is true, as pointed out in the Office Action, that the claims also refer to a "patient" and an "operator" which both refer to human beings. However, these portions of the claims merely provide the context for how the other (non-human) portions operate, in order to understand how the various components work together. This kind of claim language is permissible under § 101. Indeed, if § 101 were to preclude a claimed invention from patentability merely because it involves or may involve human participation, then just about any claim would be unpatentable.

Rejection of Claims 1-8, 10-17 and 19 Under 35 U.S.C. § 103

The Office Action (pages 4-9) rejects claims 1-8, 10-17 and 19 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,078,140 to Kwoh (hereafter "Kwoh") in view of U.S. Patent No. 6,468,226 to McIntyre IV (hereafter "McIntyre"). This group of rejected claims contains three independent claims: 1, 10 and 19. Each of those independent claims requires a guide apparatus having a connector portion coupling the guide apparatus with the imaging device and comprising a linear slider mechanism which restricts movement of the guide apparatus to a single linear path, such that a manual force applied by an operator at a gripping area during insertion of the medical device translates the medical device along a selected linear path as restricted by the linear slider mechanism.

The Office Action cites McIntyre as disclosing a connector portion coupling the guide apparatus with the imaging device and comprising a linear slider mechanism which restricts movement of the medical device along a selected linear path during insertion of a medical device by manual force. However, the analysis in the Office Action applying the claim language to the disclosure of McIntyre does not apply the claim language as a whole.

This can be seen from the following application of the claim language (with emphasis added) to the embodiment of Figures 2 and 3 of the application — which, of course, is but one of many potential embodiments:[1]

1. A system for inserting a medical device [191] into a patient, the system including . . . a guide apparatus [200] disposed on the robotic means [190] to direct movement of the medical device [191] relative to the patient, the guide apparatus [200] comprising:

a connector portion [210] coupling the guide apparatus [200] with the imaging device at a distal end [194] of the robotic means [190], **and comprising a linear slider mechanism [212] which restricts movement of the guide apparatus [200] to a single linear path [B]**;

a main body portion [220] supported relative to the imaging device by the connector portion [210];

a gripping area [230] formed at a first end of the main body portion [220], the gripping area [230] adapting the guide apparatus [200] for manual gripping by an associated operator; and,

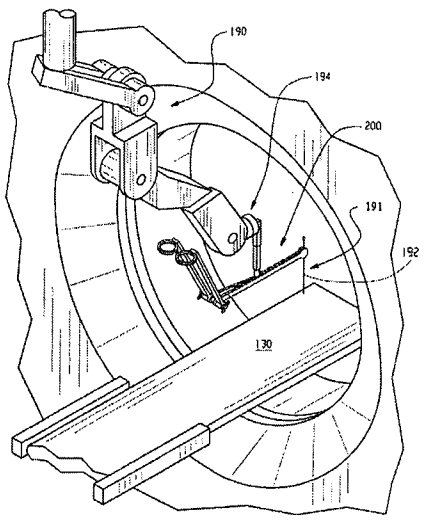


Fig. 2

a holding area [240] formed at a second end of the main body portion [220], the holding area [240] holding the medical device [191] in an orientation suitable for motion relative to said patient along a selected linear path [P], **the guide apparatus [200] being operative to translate the medical device [191] along said selected linear path [P]** in response to manual force applied by the associated operator at said gripping area [230] during insertion of the medical device [191] **as restricted by the linear slider mechanism**.

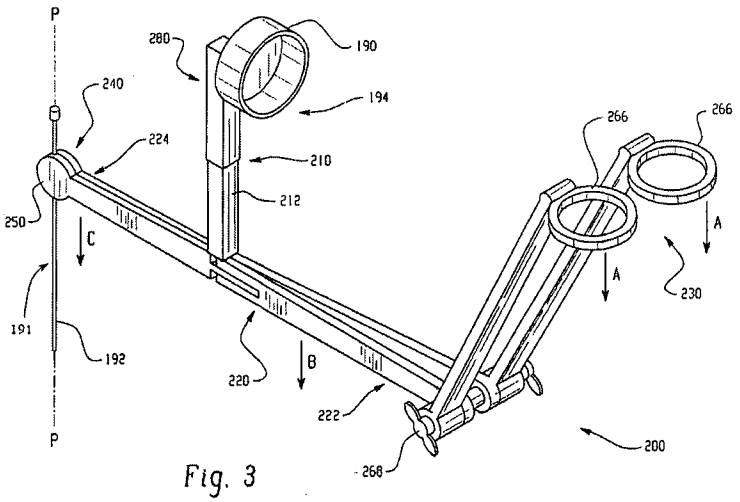


Fig. 3

As can be seen, when read as a whole, claim 1 requires that the connector portion comprises the linear slider mechanism, and that linear slider mechanism of the connector portion restricts movement of the medical device along the selected linear path in response to manual force applied at the gripping area. This is similarly true of the other independent claims 10 and 19.

[1] The Figures as shown here were submitted via a prior Amendment dated September 17, 2009.

McIntyre does not disclose such a linear slider mechanism. Even in the broadest reading of the McIntyre disclosure, including the passage at col. 10, lines 34-41, at most McIntyre describes internal linkages within the "guide apparatus" 48 / 50 to move a medical device along a linear path using manual force. McIntyre clearly does not disclose a linear slider mechanism in the connector portion to restrict movement along a linear path, as recited in the claims. Neither does Kwoh, as recognized in the Office Action.

For at least these reasons, neither Kwoh nor McIntyre discloses a guide apparatus having a connector portion comprising a linear slider mechanism which restricts movement of the guide apparatus to a single linear path, such that a manual force applied by an operator at a gripping area during insertion of the medical device translates the medical device along a selected linear path as restricted by the linear slider mechanism. Therefore, the rejections of claims 1-8, 10-17 and 19 as being unpatentably obvious over Kwoh in view of McIntyre should be reconsidered and withdrawn.

Rejection of Claims 9, 18 and 20 Under 35 U.S.C. § 103

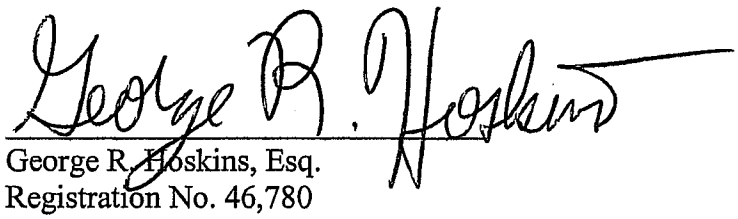
Claims 9, 18 and 20 respectively depend from independent claims 1, 10 and 19. The Office Action (pages 7-8) rejects each of these dependent claims under 35 U.S.C. § 103(a) as being unpatentable over Kwoh in view of McIntyre (discussed above in connection with the independent claims), further in view of U.S. Patent No. 3,893,813 to Johnson (hereafter "Johnson"). In each rejection, Kwoh and McIntyre were relied upon as teaching the limitations of the parent independent claims, and Johnson was cited as teaching the limitations of claims 9, 18 and 20. For at least the reasons identified above, however, the combination of Kwoh and McIntyre does not disclose each and every limitation of independent claims 1, 10 and 19. Johnson does not cure the deficiencies of Kwoh and McIntyre. Thus, it is respectfully submitted that the obviousness rejections of the dependent claims should be reconsidered and withdrawn.

Conclusion

This Amendment is fully responsive to the Office Action mailed April 21, 2011. It is respectfully submitted that the claims recite statutory subject matter and contain limitations that patentably define over the references cited by the Examiner, for the reasons provided in the remarks

above. Therefore, reconsideration and allowance of the pending claims is appropriate and respectfully requested.

Respectfully submitted,



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